JAN 1 8 2002

QUANTECH, Ltd. Total hCG Assay on the FasTraQ System
Premarket Notification

K012943

Safety and Effectiveness Summary

Company Information

Quantech Ltd.
815 Northwest Parkway Suite 100
Eagan, MN 55024
(612) 647-6370
Thomas Witty, Ph.D. – Executive Vice President, Research and Development

Contact Information

Robin J. Hellen, M.S.
Hellen Professional Services
(818) 709-5646

Product Name

Classification Name: Human Chorionic Gonadotroponin (hCG) Test System, Class II
Test Trade Name: Quantech PrePaQ Total β-hCG Cartridge
Test Common Name: PrePaQ Total β-hCG Test

System Trade Name: Quantech FasTraQ
System Common Name: FasTraQ System

CLIA Categorization

We believe the Quantech FasTraQ Automated Analyzer and PrePaQ Total β-hCG assay to be moderately categorized based on previous classifications of medical devices and analogous tests.

Substantial Equivalence

The Quantech FasTraQ Automated Analyzer and PrePaQ Total β-hCG assay are substantially equivalent to the AVDIA Centaur (predicate device) marketed by Bayer Corporation since 1997 as well as other commercially available devices and assays (i.e., Abbott AxSym and Dade Behring RxL).

Intended Use

The FasTraQ Automated Analyzer in conjunction with the PrePaQ Total hCG Cartridge is intended for use as an aid in the early detection of pregnancy where rapid, quantitative results in the emergency department or where other rapid diagnostics are required. The assay is to be used with patient whole blood samples.

Device Description

The PrePaQ Cartridge in conjunction with the FasTraQ Automated Analyer is use to quantitate hCG in whole blood using surface plasmon resonance (SPR). The Quantech PrePaQ Total β-hCG assay is based on the principle of two site, or sandwich immunoassay in combination with SPR surface mass measurement. Each PrePaQ cartridge contains a solid phase β-hCG monoclonal antibody immobilized onto a gold surface. An anti-alpha hCG polyclonal antibody conjugated to alkaline phosphatase is attached to the antigen to form the sandwich. An enhancing solution is used to further increase the mass on the surface.

Comparison of Technological Characteristics

The Quantech PrePaQ Total β-hCG assay is similar to the Bayer Centaur Total β-hCG assay as follows. Both assays are in vitro sandwich immunometric assays used for quantitative measurement to total β-hCG. Although, the Quantech assay uses whole blood, both assays report the results in mIU/ml of serum or plasma. Both assays use a β-hCG monoclonal antibody coated to a solid support. Both systems utilize a microprocessor for instrument control, data acquisition and data reduction.

Summary of Non-Clinical Performance Data

Dilution Linearity/Parallelism - The parallelism study was conducted to evaluate the linearity of the Quantech Total β-hCG Assay. Whole blood samples were separately spiked with intact hCG and serially diluted with corresponding unspiked whole blood. The average percent of expected was 111%.

Recovery - Accuracy of the Quantech Total β-hCG Assay was calculated from test results as the percentage of added analyte, corrected for endogenous analyte, recovered by the assay. After correcting for endogenous hCG content, the average recovery was 105%.

Analytical Sensitivity - Multiple duplicates of whole blood zero samples were assayed to determine the minimum quantity of hCG detectable by the Quantech Assay. The average SPR signal shift plus two standard deviations (2 S.D.) was calculated and translated into a dose. The calculated analytical sensitivity of the Quantech hCG assay is 2.5 mIU/mL.

Precision - The INTERASSAY precision was determined by evaluating three pools in triplicate on different days. The mean hCG concentrations (with % C.V.) were 57.1 (10.6%), 216.9 (8.1%), and 553.8 (5.9%) mIU/mL for the low, medium and high pools, respectively.

TOTAL IMPRECISION was determined from the interassay data, and is a combination of results from multiple runs on multiple days. The mean hCG concentrations (with % C.V.) were 57.2 (13.6%), 216.9 (12.8%), and 553.7 (9.0%) mIU/mL for the low, medium and high pools, respectively.

Interfering Substances - Physiological interference was evaluated by spiking a whole blood pools with hCG and hemoglobin, bilirubin and triglycerides at levels ten times the highest expected physiological concentration. The percent recovery of hCG was determined to be acceptable in all three solutions and no interference was noted by the endogenous substances in the Quantech PrePaQ Total β-hCG assay.

Hook Effect - Samples well beyond the standard curve range were assayed. No high dose hook effect was observed. Therefore, the Quantech Total β-hCG Assay does not give erroneously low results for grossly elevated samples up to at least 100,000 mIU/mL.

Summary of Clinical Performance Data

Normal Range - Testing of apparently healthy individuals demonstrated that the Quantech Total β-hCG Assay and the predicate device perform similarly at and below the accepted value for determination of pregnancy (greater than 25 mIU/ml). The 95% normal range of the Quantech hCG assay was 8.2 mIU/ml compared to 2.8 mIU/ml for the Centaur hCG assay.

The Quantech device demonstrates no false positive results with these apparently healthy individuals and is in 100% agreement with the predicate device.

Patient Sample Correlation - Results from human samples with values distributed throughout the quantitative range of the Quantech hCG assay, were compared with those obtained with a commercially available methods. The internal paired sample comparison resulted in a correlation coefficient of 0.97 (slope = 0.67, intercept = 1.47) with the Bayer Centaur (predicate device). The external paired sample comparison resulted in a correlation coefficient of 0.93 (slope 0.89, intercept –1.7992) with the Abbott AxSym.

Conclusions Drawn From Performance Tests

The Quantech Total β-hCG Assay provides results which are internally accurate, unaffected by ordinary variation of sample matrix and equivalent to the results obtained using the approved device in a valid laboratory setting.

Additionally, both clinically-based studies (normal range, patient correlation) demonstrated essential equivalence between the devices as measured by their correlation and the degree to which assay results are linearly related to one another over a broad range of values. Likewise, the normal range evaluation provided empirical evidence that the assay value is similar for both devices, and in agreement with published data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quantech Limited
c/o Ms. Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, CA 91325

JAN 18 2002

Re: k012943
Trade/Device Name: The Quantech FasTraQ Automated Analyzer, and
The Quantech PrePaQ Total hCG Test Cartridge.
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: NAL
Dated: November 16, 2001
Received: November 19, 2001

Dear Ms. Hellen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Statement for Indications for Use

510(k) Number (if known): K012943

Device Name: Quantech FasTraQ Automated System:
FasTraQ Automated Analyzer and the
PrePaQ Total hCG Test Cartridge

Indications for Use:

- **The Quantech *PrePaQ Total hCG Test Cartridge* is intended for use with the *FasTraQ Automated Analyzer* to provide rapid, quantitative measurement of human chorionic gonadotropin (hCG) in whole blood for the determination of pregnancy. The Analyzer and hCG Cartridge combine ease of use and rapid turnaround time with laboratory-quality performance and reliability. The FasTraQ System is designed for use by non-laboratory medical professionals in emergency departments, STAT or central laboratories.**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012943

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over the Counter Use:** _____